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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/747,774	12/21/2000	Christine A. Klein	CPI-012CP5DV	5116
959	7590	04/19/2004	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			LI, RUIXIANG	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/747,774

Applicant(s)

KLEIN ET AL.

Examiner

Ruixiang Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,8-11,17,25-27,36,37,39,50,51 and 53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,8-11,17,25-27,36,37,39,50,51 and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO AMENDMENT

I. Status of Application, Amendments, and/or Claims

The amendment filed on January 2, 2004 has been entered. Claims 3, 4, 6, 7, 12-16, 18-24, 28-35, 38, 40-49, and 52 have been canceled. Claims 1, 2, 5, 8-11, 17, 26, 27, 36, 37, 39, 50, and 51 have been amended. Claims 1, 2, 5, 8-11, 17, 25-27, 36, 37, 39, 50, 51, and 53 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

II. Withdrawn Objections and/or Rejections

Applicants' cancellation of claims 4, 7, 22, 23, 32, 35, 48, and 49 has made all the rejections and objections set forth in the previous office action moot.

The rejection of claims 1, 2, 5, 8-11, 17, 25-27, 36, 37, 39, 50, 51, and 53 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 12, 16, 18-20, and 23 of U.S. Patent No. 6,100,042 has been withdrawn in view of Applicants' amendment to claims by reciting an orphan cell surface receptor.

The rejection of claims 1, 2, 5, 8-11, 17, 25-27, 36, 37, 39, 50, 51, and 53 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21, 23, 24, 26, 28, 29, 31, 32, 34, and 36 of U.S. Patent No. 5,

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789, 184 or U.S. Patent No. 5,876,951 has been withdrawn in view of Applicants' amendment to claims by reciting an orphan cell surface receptor.

The rejection of claims 1, 2, 5, 8-11, 17, 25-27, 36, 37, 39, 50, 51, and 53 under 35 U.S.C. §112, 2nd paragraph, as set forth at pages 12-13 of the previous office action (Paper No. 20, May 27, 2003) has been withdrawn in view of Applicants' amendment to claims 1, 2, 5, 8-11, 17, 26, 27, 36, 37, 39, 50, and 51.

The objection to claims 1, 2, 5, 8-11, 17, 25-27, 36, 37, 39, 50, 51, and 53 for minor informalities as set forth at page 15 of the previous office action (Paper No. 20, May 27, 2003) has been withdrawn in view of Applicants' amendment to claims 1, 2, 5, 8-11, 17, 26, 27, 36, 37, 39, 50, and 51.

III. Substitute Specification

The Examiner acknowledges Applicants' statement that the substitute specification filed August 16, 2002 in paper No. 12 under 37 CFR 1.125(b) contains no new matter. The substitute specification has been entered.

IV. Claim Rejections under 35 USC § 101

The rejection of canceled claims 22, 32, and 48 under 35 U.S.C. §101 is applied to the amended claims 1, 2, 5, 8-11, 17, 25-27, 36, 37, 39, 50, 51, and 53. The amended claims are drawn to a mixture of recombinant cells comprising an orphan cell surface receptor. The claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility for the reasons set forth in the previous office action (Paper No. 20, May 27, 2003).

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Beginning at the bottom of page 7 of Applicants' response, Applicants argue that the test polypeptides generated by the recombinant cells of the instant invention may be used to identify the polypeptides that react with orphan cell surface receptors. Applicants submit that the pending claims provide a step in the process for the identification of the function of orphan cell surface receptors.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. While the recombinant cells comprising an orphan cell surface receptor can be a useful research tool for identification the function of an orphan cell surface receptor, such a research use is not a substantial utility. See, e.g., *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966) wherein a research utility was not considered a "substantial utility."

At the 2nd paragraph of page 8, Applicants argue that orphan receptors have been conserved in evolution and may thus be found throughout the human body. Clearly, orphan receptors are involved in important biological functions.

Applicants' argument has been fully considered, but is not deemed to be persuasive because an orphan receptor, by its definition, does not have a defined ligand and a specific biological function whereas identification of the biological function of the orphan receptor requires further research, which is not allowed under 35 U.S.C. § 101.

At the 3rd paragraph of page 8, Applicants argue that the recombinant cells of the present invention may also provide valuable information about the ligand that activates the orphan cell surface receptor.

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Applicants' argument has been fully considered, but is not deemed to be persuasive because such a use is considered a research use and is not a substantial utility, as noted above.

V. Claim Rejections under 35 USC § 112, 1st paragraph (Enablement)

Claims 1, 2, 5, 8-11, 17, 25-27, 36, 37, 39, 50, 51, and 53 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Furthermore, the previous office action stated that even if the claimed invention were to have a patentable utility, the instant disclosure would not be found to be enabling for the full scope of the invention. It is noted that Applicants have amended claims 8-11, 17, 25-27, 36, 37, 39, 50, 51, and 53 to limit the invention to a mixture of recombinant yeast cells. However, claims 1, 2, and 5 still recite a mixture of recombinant cells. The issue of scope of enablement remains.

Applicants argue that the teachings in the specification and knowledge available to one of ordinary skill in the art at the time of filing are sufficient to make the recombinant cells of the claimed invention. Applicants submit that Applicants have provided working examples that disclose how to make and use the claimed recombinant cells of the instant invention.

Applicants' argument has been fully considered, but is not deemed to be persuasive because all the working examples and the directions/guidance provided in

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the specification are limited to preparation and use of a mixture of recombinant autocrine yeast cells that express cell surface GPCR and comprise a pheromone response pathway. The instant disclosure fails to provide sufficient guidance and working examples on how to make and use a mixture of any other recombinant cells comprising any other cell surface receptors or recombinant genes encoding any other cell surface receptors that are involved in any other signal transduction pathways.

In view of Applicants' species election of yeast cells, it is suggested that claims 1, 2, and 5 be amended to recite a mixture of recombinant yeast cells.

VI. Claim Rejections under 35 USC § 103 (a)

The rejection of claims 1, 2, 5, 8-11, 17, 25-27, 36, 39, 50, and 53 under 35 U.S.C. 103(a) as being unpatentable over King et al. (Science 250:121-123, October 5, 1990) in view of Devlin et al. (Science 249:404-406, July 27, 1990), Scott et al. (Science 249:386-390, July 27, 1990), Cwirla et al. (Proc. Natl. Acad. Sci. USA, 87: 6378-6382, 1990), and Ladner et al. (U. S. Patent No. 5,096,815, March 17, 1992), as set forth in the previous office action (Paper No. 20, May 27, 2003), is maintained.

Applicants argue that none of the cited references teach or suggest, either alone or in combination, the use of an autocrine system to identify specific polypeptide that react with orphan cell surface receptors.

Applicants' argument has been fully considered, but is not deemed to be persuasive because, while the cited references alone do not teach the claimed invention, the cited references in combination do teach or suggest the use of an autocrine system to identify specific polypeptide that react with orphan cell surface

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receptors. It would have been obvious to an artisan at the time the invention was made to construct a library of random peptides taught by Devlin et al., Scott et al., Cwirla et al., or Ladner et al. in the yeast cells taught by King et al. to produce a mixture of recombinant yeast cells as recited in the instant claims. One would have been motivated to do so because use of peptide libraries is useful and efficient in screening for peptide ligands as taught by Devlin et al., Scott et al., Cwirla et al., or Ladner et al.

VII. Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875.

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The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (571) 272-0871. The fax number for this Group is (703) 872-9306.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Ruixiang Li
Examiner
April 12, 2004

A handwritten signature in black ink, appearing to read "Lorraine Spector", with a large, stylized initial "L".

LORRAINE SPECTOR
PRIMARY EXAMINER